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Standards of accountability for consent in research

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I.

It is fitting that this conference on ethics in neurobiological research takes place as we open 1995. This year marks the 50th anniversary of the end of the Second World War and thus the threshold of modern concern about the ethics of biomedical research. The first product of this concern, the Nuremburg Code, has remained a benchmark for the regulation of biomedical research since 1949 (*United States v. Brandt*).[1] The Code, like the Declaration of Independence, is a document more talked about than read. Yet, like the Declaration, its first, unequivocal sentence, set the tone for the future: "The voluntary consent of the human subject is absolutely essential." Despite its flaws, the Nuremburg Code compares favorably with many of the most explicit contemporary documents, and is indeed more protective of human subjects in experimentation than many codes adopted since.

Today the principle of informed consent in human subject research has become part of the fabric of regulation of research practices. It would seem that, as a result, the violations of the principle that led to the scandals of the past half-century—Tuskegee, the Jewish Chronic Disease Hospital case, radiation research and the rest—would be behind us. Yet new research scandals involving a faulty consent process in human subject research keep reappearing, most recently in the UCLA drug discontinuation experiments, which brought about a rebuke from the Office of Protection from Research Risks, a critique from Jay Katz (Katz 1993)[2] a front page story in the New York Times (New York Times 1994)[3] and even an editorial in that newspaper (New York Times 1994).[4]

The difficulties in the process of informed consent are well known and well documented. Some investigators resist a thoroughgoing consent process because they fear it will discourage participation in the research project, lead to unnecessary misunderstandings or interfere with efforts at randomization, all of which

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impede discovery of new and effective treatments for the afflictions of our day. Appelbaum and Roth, for example, found that of 17 investigators they surveyed who worked with human subjects only half believed in the importance of informed consent as an ethical or practical principle, and the others rejected it as an unattainable intrusion on the conduct of the research.[5] Further, as Katz observes, researchers tend to blur the distinction between research and clinical practice, and with it, the differentiated roles of physician and the investigator. This leads to insufficient and sometimes misleading discussion with subjects. In the UCLA case, for example, he identifies manipulation of subjects' consent, failure to distinguish trivial and non-trivial risks, lack of explanation of the incidence or severity of predictable risks, and failure to explain the risks and benefits of non-participation (Katz 1993). Indeed, he argues that inadequate obtaining of consent is the norm, not the exception.

To be sure, today these problems are usually of a different order than the injection of live cancer cells and other grotesque practices Henry Beecher identified in 1966 (Beecher 1966).[6] Still, as in Beecher's day, problems of consent persist in the research conducted by prominent researchers at leading institutions. Moreover, they continue in the face of federal regulations establishing rules for informed consent and establishing Institutional Review Boards to enforce them. Some of the problems no doubt derive, as many have argued, from flaws in the regulations and in their implementation, e.g., in-bred IRB's, failure to attend to special risks among subjects whose competence to consent is questionable, and undue focus on consent forms rather than the consent process.

But I believe another factor is at work as well. At least part of the reason problems of consent in research persist is confusion about whose standards of accountability in research apply. Are they the standards of the research field or of the larger society? Is the proper analogy for the accountability of the researcher medical malpractice, where standards traditionally derive from the practices of the community of physicians, or civil rights law, where statutory or judicially created standards of discrimination derive from the larger society? The existence of federal regulations that constitute a body of law tends to mask these questions rather than do away with them. It is my purpose in this paper to identify the conflict and propose a resolution.

II.

I propose to illustrate these questions in an unusual way, through a piece of litigation in the late 1980's in which I was personally involved that pitted two of the country's leading authorities on the history of informed consent in biomedical research against each other, under oath, on the subject of the applicable standard in judging a researcher's conduct. Indeed, each expert was cross-examined at length, one by me.

The case was *Orlikow v. United States*,[7] where nine former patients of Dr. Ewen Cameron of McGill University in Montreal sought damages from the United States for injuries they claimed to have received as a result of Central Intelligence Agency funding of radical experiments performed on them in the 1950's by Dr. Cameron

without their informed consent. I was one of the lawyers for the nine plaintiffs. Social historian David Rothman, whose many writings on biomedical ethics include *Strangers at the Bedside* (Rothman 1991),[8] was our expert. Tom Beauchamp, who, with Ruth Faden, wrote *A History and Theory of Informed Consent*,[9] was an expert for the government.

Cameron, who died in 1967, is a fascinating figure, one of the most renowned psychiatrists of his day and once president of the American Psychiatric Association. He was a pioneer of social psychiatry and an innovator who developed the day hospital. Cameron was one of the psychiatrists commissioned by Nuremburg authorities to interview Rudolph Hess to assess his competence to stand trial. Indeed, he was deeply affected by the experience of Nazism and wanted to find ways to change thought patterns that be believed were destructive either to an individual's mental health or the democratic social fabric. His science, however, was deeply flawed. In the early 1950's, he developed experiments designed to test theories about changing human thought patterns and personality through a technique called "psychic driving," which involved the repetition of a recorded message a few seconds in length thousands of times for up to 20 hours at a time. Using private patients who came to him for treatment for anxiety, depression and other mental health problems, he sought to "implant"—his word—these new ideas and personality characteristics into the subject. He published the first of many articles on the subject, appropriately enough entitled "Psychic Driving," in the *American Journal of Psychiatry* in January, 1956.

He neither disclosed to his patients that he was engaged in research, or indeed in any unconventional form of therapy, nor sought anyone's consent for it. The patients were competent to make decisions about their lives but were never told that experiments, much less radical experiments, were being conducted on them, that Cameron's research interests included clinically untested therapies that could cause harm, nor that they would not be able to stop the research by a subsequent refusal.

In the course of his research, Cameron soon enough discovered that his patients resisted the repeated messages. Some refused to participate; some actually ran away. So Cameron sought to develop techniques to lower both conscious and unconscious resistance to listening to the messages for hours on end. He also looked for new ways to "break down" behavior by reducing the patient to a state of complete confusion and helplessness. The most notorious of these methods was "depatterning," Cameron's term for achieving a state "where the patient has developed an organic brain syndrome with acute confusion, disorientation and interference with his learned habits of eating and bladder and bowel control." Cameron wrote that, at this point, the patient's "conceptual span is limited to a few minutes and to entirely concrete events" and that "he cannot conceptualize where he is, nor does he recognize those who treat him."

To achieve this, Cameron used massive regressive electro-convulsive therapy combined with drugs that sought to reduce the person to an infantile state. He also used barbiturate-induced sleep for periods exceeding 30 days, LSD, sensory deprivation and curare.

Cameron published papers concerning this work in major psychiatric journals and lectured widely about it. In the mid-1950's, his Psychic Driving article came to

the attention of the CIA, which was then interested in brainwashing techniques allegedly used by the Chinese in the Korean War. Using a front organization called the Society for the Investigation of Human Ecology, the CIA invited Cameron to submit a research grant proposal. Cameron's proposal included additional psychic driving experiments that included the following elements:

1. Breaking down of ongoing patterns of behavior—depatterning—through intensive electroshocks.
2. Intensive repetition (16 hours a day for 6–7 days) of the messages.
3. Keeping the patient in partial sensory deprivation.
4. Following the psychic driving with 7–10 days of barbiturate-induced sleep.

He also proposed to put LSD into the mix and inactivate the patient through the use of curare. The CIA funded the proposal in 1957.

It was not until the late 1970's, following Senate Intelligence Committee hearings, Freedom of Information Act requests by an enterprising reporter, John Marks,[10] and reports of the CIA documents in the New York Times, that the connection between the CIA and Cameron came to light. By then, Cameron had died, but nine of Cameron's former patients sued the United States, claiming that they had been harmed by experiments funded by the CIA. They alleged, among other wrongs, that the CIA had acted negligently in funding experimentation on patients without requiring and assuring their informed consent to participate in it. As the case proceeded through discovery, the CIA witnesses conceded that they had no interest in protecting Cameron's patients, had not considered the question of informed consent and had made no effort to require any safeguards of the subjects or to require reports of the status of the subjects.[11]

Nevertheless, the government denied liability. Among other defenses, it argued that the CIA's conduct had to be judged by the ethical standards of the time, which it said, did not require informed consent for biomedical research with human subjects. Aside from differences about the appropriate legal standard deriving from relevant cases, the parties differed about what the ethics of research at the time of Cameron's experiments required regarding informed consent. Each side brought in an expert.

Enter Professors Rothman for the plaintiffs and Beauchamp for the CIA. They agreed on some basic facts, particularly that despite the importance of the Nuremburg Code and the principles on which it was based, during the 1950's it garnered little attention from the American research community. Professor Rothman indeed had recently written a retrospective article on Henry Beecher's famous 1966 piece that agreed with Beecher's view that his examples were not anomalies but were fairly representative of practice at the time (Rothman 1987).[12]

Agreement ended there, however, and I believe their disagreement about the 1950's is relevant now because it demonstrates different standards and approaches for holding researchers accountable for obtaining or failing to obtain consent from research subjects.

Professor Rothman's position was that by the 1950's, the necessity of obtaining the voluntary consent of human subjects to participation in research had become part of the fabric of standards governing that research. The affidavit he submitted in the case traced the history of consent principles in human experimentation from the end of the nineteenth century through Walter Reed's research on yellow fever,

the Second World War and into the 1950's. In his words, both before and after the adoption of the Nuremburg Code, the "voluntary consent requirement" was part of the "generally accepted principles applicable to medical experimentation." The affidavit also stated:

> [D]uring the 1950's, there was a recognized obligation on the part of entities financing, sponsoring or conducting medical experimentation to adopt ethical standards reflecting the principles set out in the Nuremburg Code, particularly the informed consent requirement; and to make inquiry and to ascertain the competence and prudence in dealing with research subjects of those conducting medical experimentation on their behalf.[13]

Professor Rothman concluded his affidavit by stating that "by the 1950's it was clearly irresponsible for a physician to conduct experiments upon patients without obtaining their voluntary consent to be research subjects."

Professor Rothman agreed that the principle of voluntary consent was frequently violated; indeed, he had just written on that very subject. In his view, however, the many deviations from Nuremburg's principles by researchers did not allow a particular investigator who failed to follow them to escape accountability under those principles. While not discounting contemporary practices in making the decision about accountability, he stressed that extensive violations of a norm do not disprove its existence. Moreover, as stated in his deposition, in his view, the "relevant body by which one judges an ethic is not, in the case at hand, exclusively medical. An ethic guiding human experimentation is not judged only by whether the medical community adheres to it, because there are other communities that are relevant as well." For him, those other communities especially included the larger public from which subjects were selected. Thus, for him, the fact that voluntary consent had not become embedded in the ethos of the research community was not the least dispositive, since the standard derived from a larger community.

Both these points, he said, were apparent in Henry Beecher's 1966 article citing examples of clearly unethical research and the response to it. Professor Rothman explained that Beecher's criticism of unethical research "assumes the existence of the norm" and contended that the public outrage the article generated demonstrated the existence of standards outside the narrow community of the field of medical researchers.

Professor Rothman has made these points in a more elaborate way in *Strangers at the Bedside*, his history of the emergence of biomedical ethics in the modern era. In commenting on the critical responses to Henry Beecher's exposes of unethical research, Rothman states:

> The more popular objection (which can still be heard among investigators today) was that he had unfairly assessed 1950s practices in terms of the moral standards of a later era. To these critics, the investigators that Beecher had singled out were pioneers, working before standards were set for human investigation, before it was considered necessary to inform subjects about the research and obtain their formal consent to participation. The enterprise of human investigation was so novel that research ethics had been necessarily primitive and underdeveloped.
>
> However popular—and, on the surface, appealing—that retort is, it not only fails to address the disjuncture between public expectations and researchers' behavior but is woefully short on historical perspective. If the activity was so new and the state of ethics so crude, why did outsiders shudder as they read about the experiments?[14]

Professor Rothman's position was similar to that taken by the Tuskegee Syphilis Study Ad Hoc Panel, which concluded that the failure to obtain consent of the

subjects was "ethically unjustified" even in 1932.[15] Similarly, in the well-known Jewish Chronic Disease Hospital case, in the 1960's, a physician was disciplined for violating consent rules despite the absence of the peer review and regulatory requirements concerning consent which now govern experimental research.

Finally, Professor Rothman cited Defense Department policies for funding biomedical research as reinforcing the ethical argument of informed consent. In February, 1953, the Secretary of Defense adopted the Nuremburg Code for atomic, biological and chemical agents research, distributing the memo to the Secretaries of the Army, Air Force and Navy and to the Research and Development Board. The policy required the Secretary of the service conducting the research to approve such experiments. On June 30, 1953, the Chief of Staff of the Army adopted a set of standards distributed to the Chief Chemical Officer and the Surgeon General of the Army governing the use of volunteers in research concerning atomic, biological, and/or chemical warfare defense. The nine-page document recited virtually verbatim the entire Nuremburg Code, including its rules on consent:

> The voluntary consent of the human subject is absolutely essential. This means that the person involved should have the legal capacity to give consent, should be so situated as to be able to exercise free power of choice without the intervention of any element of force, fraud, deceit, duress, overreaching, or other ulterior form of constraint or coercion and should have sufficient knowledge and comprehension of the elements of the subject matter as to make an understanding and enlightened decision. This latter element requires that before the acceptance of an affirmative decision by the experimental subject there should be known to him the nature, duration, and purpose of the experiment; the method and means by which it is to be conducted; all inconveniences and hazards reasonably to be expected; and the effects upon his health or person which may possibly come from his participation in the experiment.

The memorandum explained that consent must be in writing and witnessed; that the Secretary of any Service must take responsibility for adherence to consent requirements; that the "duty and responsibility for ascertaining the quality of the consent rests upon the person who initiates, directs or engages in the experiment" and that this duty is a "personal duty and responsibility which may not be delegated to another with impunity." It also states that volunteers must be males under the age of 35, "with no mental or physical diseases." Finally, the memorandum established a series of procedures for implementing these requirements.

Clearly, the CIA did not follow these rules. Recent revelations have provided yet additional examples that these standards were not followed in government-conducted research on the effects of nuclear radiation. The existence of these government-adopted rules, however, reinforced Professor Rothman's view that the CIA could be held accountable for failing to adhere to the principles of informed consent in funding Cameron's work, even if the Defense Department did not properly implement the rules.

Tom Beauchamp provided an entirely different account of the standards applicable to judging the conduct of Cameron or other researchers in the 1950's. Professor Beauchamp differentiated between what he called transcendent standards identified by morally acute institutions and individuals and the standards adopted by the ethos of the research field. He agreed that morally acute individuals like Andrew Ivy, an author of the Nuremburg Code and a resolution adopted by the American Medical Association in 1946 that required consent of research subjects, demanded informed consent of human subjects in biomedical research around the

time of World War II, but he denied that those principles had become part of the research ethos. As Professor Beauchamp put it in his deposition, "it was pretty much left up to the individual investigator to figure out in the context in which the individual investigator was doing the research the difference between it being decent or it not being decent, it being justifiable or not it being justifiable to do this."

Professor Beauchamp held that one could judge a person's conduct from either perspective, the morally acute individual or institution or the ethos of the time. But in the absence of binding regulations, he held that a person could be held professionally accountable in some relevant way (e.g., imposing a sanction) only by applying the standards derived from the ethos of the time. These in turn derive from "what the prevailing practices were, much in the same way in which a court might today consider whether or not it was a breach of practice by asking what the practices are." Put another way, judgments can be made based on what "the normal practitioner would know to be acceptable." And in his view, those prevailing practices among biomedical researchers did not require informed consent until well into the 1970's at the earliest. While allowing that we could choose to use a different standard of judgment, e.g., the morally acute individual, in general Professor Beauchamp did not believe it fair to do so. Rather, he claimed, judgments should be made only according to the then-current "ethos" in the medical research community.

Accordingly, in making judgments about Cameron (and government funding of Cameron) it was important to Beauchamp that "what [Cameron] was doing was fairly common in psychiatric research, not in terms of his particular methodology, but in the sense that there was a great need to come up with cures and therapies for desperate patients or very sick patients." He added, "And I would have thought that Dr. Cameron was a part of that ethos. And you might see it as a good ethos or as a bad ethos. Again I am not making any judgment on that. But he was a part of that."

Thus, Professor Beauchamp testified that in making a decision whether to hold Cameron or his funders accountable for the injuries to the nine plaintiffs because of lack of informed consent, the Nuremburg Code and its principles should not be applied because they were not part of the research ethos at the time. "Should Dr. Cameron have done better [in obtaining consent] ... irrespective of what the prevailing practices were among psychiatrists at the time; should he really have transcended those standards and told his patients more than he did, that is the way I would interpret your question.... I think that would be asking too much of the man in my judgment."

I also asked Professor Beauchamp whether the government's decision to fund the research could be judged under the Secretary of Defense's memorandum for government-sponsored atomic, biological and chemical research with human subjects. He responded that since the Secretary's memoranda were largely ignored, they were not the basis for making a judgment. "I think that is the fallacy of thinking that something becomes a written rule, that it therefore becomes the prevailing practice." This exchange followed:

Q. But here, it was a government policy of the Secretary of Defense?

A. Yes. But you see, the critical question to me is not who passed the policy and is

it on the books, but was it filtered down. Was there any mechanism for letting the people who had to then put it into practice put it into practice, other than say publishing it in a journal or something like that. To me, that is not an organ of dissemination that eventuates in any changes in practice.

III.

The court in the *Orlikow* case never resolved which standards of accountability should apply because the parties settled. There was a denouement, though. Harvey Weinstein, a psychiatrist and son of one of the plaintiffs, pressured the American Psychiatric Association for a condemnation of the conduct of its former President. Finally, in May, 1989, Paul Fink, President of the APA, issued a statement in which he said that "In my view, the research ... could not be conducted today, and should not have been conducted then, no matter how frustrated and desperate researchers were to find treatments for those with mental illness" (Weinstein).[16]

But what are we to make of the Rothman/Beauchamp disagreement? Does it illuminate any of our current controversies? At one level, the disagreement between them is simply about history: what was the status of the requirement of informed consent for human research subjects in the 1950's?

At another level, though, it sheds light on the nature of the disagreements that both led to and pervade this conference, disagreements that are based in part on the different concepts of accountability relied upon by Professors Rothman and Beauchamp. Professor Beauchamp essentially adopted a malpractice-type standard for accountability in research with human subjects, that is, whether the conduct at issue is consistent with the practices of colleagues in the research field. By contrast, Professor Rothman, like Beecher and the Tuskegee panel, viewed the obligation of practitioners far more broadly. In his view, standards of accountability do not and cannot derive exclusively from within the medical profession, but from the larger society. Moreover, researchers are expected to be aware of the principles of research ethics, including informed consent, that have been articulated through codes, journals, and other forms of discussion. Finally, in Rothman's view the fact that others in the field do not adhere to those principles in their research practices is no defense in a proceeding to hold a particular researcher accountable.

Even in a world now dominated by regulation of informed consent in research, the tension between the two views persists. The apparatus of regulation, including Institutional Review Boards and written consent forms, would appear to reflect the triumph of the view that the larger society, not the research community, controls the ethics of biomedical research. But the regulatory system operates through mechanisms that enable, even encourage, filling in the large interstices in the ethics of consent—the nature of the disclosures, the process of consent, the overall relationship to the subject—from within the research community. The values and approaches of that community thus can continue to exert a large influence over the approach to accountability for consent in research. Moreover, the very structure of the regulatory scheme tends to insulate the public from a meaningful role in the review process. The central vehicle for supervision, the IRB, is often dominated by

institutional insiders and those who engage in research themselves. The public agency, OPRR, eschews oversight in the absence of a complaint. In such a system, the perpetuation of standards of accountability that emerge from within the research community itself should not be a surprise.

How great are the differences in the two worlds? Surely practice-based standards today are far different from what they were in 1950, or even 1970, and far closer to the autonomy-based approaches to informed consent generally embraced by the larger public. In this paper, I can only sketch some differences between public and research-community-based standards, but I do suggest that as evidenced in writings, in practices and at this conference, research-community standards sometimes differ from those that stress the autonomy of the research subject.

A brief paper written by William Wirshing, Director of the Movement Disorders Laboratory at UCLA, no doubt written in the wake of the controversy there, illustrates this point. Wirshing interprets his obligations as a researcher not to make informed consent and patient protection absolute requirements, but to engage in the task of "balancing rights and benefits" of research. He argues that "most clinical experimentation takes place in a setting that is safer, better funded, and far more enlightened and informed than nonresearch medical treatment" and complains that research is hampered by "a process that has become so legalistically elaborate that it is difficult if not impossible to 'properly' inform a psychiatrically ill patient." The result is for investigators to "favor to a fault the safety side of the risk equation" leading to the possibility, in his view, of "a decade of research marked by profound insecurity and constipation."[17] In short, Wirshing seeks to balance the rights of research subjects against the value of the research, an approach significantly different from one that asserts autonomy above all. The views expressed at the conference illustrate the point as well. Some of the researchers present responded to concerns about consent with a defense of the legitimacy of the research itself, as though the good ends of the research could temper the need for thorough disclosure and consent. They questioned both the wisdom of external standards of accountability and the content of such standards.

It is difficult to assess how representative these views are, but I believe we will not make progress until differences in the approaches to accountability are openly acknowledged and confronted. Ultimately, field-based standards of accountability in research that persist among researchers cannot be sustained because they cannot meet the standards the public demands—and has every right to demand. Researchers have no special expertise in research ethics and the public has too great a stake in the protection of human subjects and in the manner in which subjects are treated in the research process. Moreover, the researcher cannot possess special ethical expertise because of the enduring conflict between the researcher's fundamental interest in the advancement of knowledge and the subject's interest in disclosure and good treatment. As Katz has pointed out so often, this inherent conflict of interest underlies many of the dilemmas of the researcher-subject relationship.

In the absence of a recognition of differences, we can anticipate further conflict and calls for ever more detailed requirements, including specific changes in the OPRR regulations designed to improve the consent process (Goldner 1993).[18] More formal regulation may be the only way to bring to an end the difference between

socially-imposed and research-community-based standards, but I believe it would be better for the research community to embrace standards from the larger public, and join with it in designing consent processes and in evaluating compliance with those processes that recognize the legitimacy of a public standard. It is time to abandon research community-based approaches to accountability for subject consent in research.

NOTES

1. United States v. Brandt (The Medical Case), II Trials of War Criminals Before the Nuremburg Military Tribunal Under Control Council Law No. 10, at 181–182 (1949).
2. Katz, J. Human Experimentation and Human Rights. *St. Louis University Law Journal* 1993; 38:7–54.
3. New York Times, March 10, 1994.
4. New York Times, March 14, 1994.
5. Appelbaum, P.S. and Roth, L.H. The Structure of Informed Consent in Psychiatric Research. *Behavioral Sciences and the Law* 1983; 1:9–19.
6. Beecher, H. Ethics and Clinical Research, *New England Journal of Medicine* 1966; 274:1354–1360.
7. Orlikow v. United States, 682 F. Supp. 77 (D.D.C. 1988).
   Although the case has received little attention in the United States, it was a cause celebre in Canada. Three books were published about the case in Canada, one of which was also republished here. The two exclusively Canadian books are Ann Collins, *In the Sleep Room, The Story of the CIA Brainwashing Experiments in Canada* (Toronto: Lester and Orpen Dennys, 1988); Don Gillmor, *I Swear by Apollo, Dr. Ewen Cameron and the CIA-Brainwashing Experiments* (Montreal: Eden Press, 1987). The third book, by a psychiatrist who is the son of one of the victims, is Harvey Weinstein, *Psychiatry and the CIA: Victims of Mind Control* (Washington: American Psychiatric Press, 1990).
8. Rothman, D. *Strangers at the Bedside* (New York: Basic Books, 1991).
9. Faden, R.R. and Beauchamp, T.L., *A History and Theory of Informed Consent* (New York: Oxford, 1986).
10. Marks, J. *The Search for the Manchurian Candidate: The CIA and Mind Control* (New York: McGraw Hill 1980).
11. Rauh, J. and Turner, J. Anatomy of a Public Interest Case Against the CIA. *Hamline Journal of Public Law and Policy* 1990; 11: 307–363.
12. Rothman, D. Ethics and Human Experimentation: Henry Beecher Revisited. *New England Journal of Medicine* 1987; 317:1195–1199.
13. The affidavit is quoted at Rauh and Turner at 339.
14. Rothman (1991) at 16–17.
15. Jones, J. *Bad Blood* (New York: Free Press 1981) at 210.
16. Quoted in Weinstein at 278. The Canadian Psychiatric Association refused to go this far, stating only that Cameron's research could not have been conducted today.
17. William C. Wirshing, In a Perfect World None of This Would Concern Us, *The Journal of the California Alliance of the Mentally Ill*, 1994; 5:30.
18. See, for example, Jesse Goldner, An Overview of Legal Controls on Human Experimentation and the Regulatory Implications of Taking Jay Katz Seriously, *St. Louis University Law Journal* 1993; 38: 63–134.